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EXAMINER

SCHILLINGER, ANN M

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| ART UNIT | PAPER NUMBER |
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3774

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12/09/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary**Application No.**

10/540,306

Applicant(s)

O'ROURKE ET AL.

Examiner

ANN SCHILLINGER

Art Unit

3774

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 28 August 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-29 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-29 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SF/ICE)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 8-12, 14, 17, 18 are rejected under 35 U.S.C. 102(b) as being anticipated by Barefoot et al. (US Pat. No. 3,726,279). Barefoot et al. discloses the following of the claimed invention: a method of treating a stiffened blood vessel to help it resume normal function, said method comprising at least substantially encasing a stiffened portion of said blood vessel (col. 2, line 65 through col. 3, line 14) with an elastic membrane formed of biocompatible material (10) such that said membrane engages said stiffened portion of said blood vessel to thereby reduce the external diameter of said stiffened portion of said blood vessel. The opposing end portions of the membrane sheet may be secured by suturing (27) or with a clamp (30, Figure 9). Barefoot et al. also discloses that the membrane may be in the form of a spiral (please see Figure 6).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 2-4 are rejected under 35 U.S.C. 103(a) as being unpatentable over Barefoot et al. in view of Khanghani et al. (US Pat. No. 6,984,201). Barefoot et al. teaches the invention

substantially as claimed, however, Barefoot et al. does not teach placing the device on an artery such as the ascending aorta. Khanghani et al. teaches a blood circulation device on the ascending aorta in col. 9, lines 8-29 for the purpose of properly maintaining the heart's bloodflow. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to use the device of Barefoot et al. on the ascending aorta in order to properly maintain the heart's bloodflow.

Claims 5, 6, 28, and 29 are rejected under 35 U.S.C. 103(a) as being unpatentable over Barefoot et al. in view of Chuter (US Pat. No. 5,387,235). Barefoot et al. teaches the invention substantially as claimed, however, Barefoot et al. does not teach constructing the device from a graft of woven polyester. Chuter teaches a stent with a woven polyester graft in col. 9, lines 12-43 for the purpose of utilizing the material's elasticity. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the device of Barefoot et al. by constructing it from a graft of woven polyester in order to utilize the material's elasticity.

Claim 7 is rejected under 35 U.S.C. 103(a) as being unpatentable over Barefoot et al. in view of Von Oepen (US Pub. No. 2002/0151959). Barefoot et al. teaches the invention substantially as claimed, however, Barefoot et al. does not teach dilating the vessel prior to treatment. Von Oepen teaches a stent where the vessel is dilated prior to treatment in paragraphs 0001-0002 for the purpose of preventing the vessel from closing. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the process of Barefoot et al. by dilating the vessel prior to treatment in order to prevent the vessel from closing.

Claim 13 is rejected under 35 U.S.C. 103(a) as being unpatentable over Barefoot et al. in view of Spaulding (US Pat. No. 5,304,200). Barefoot et al. teaches the invention substantially as claimed, however, Barefoot et al. does not teach welding the ends of the prosthesis. Spaulding teaches a stent with welded ends in col. 5, lines 13-49 for the purpose of securing the prosthesis in its desired shape. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the device of Barefoot et al. by welding the ends of the prosthesis in order to secure the prosthesis in its desired shape.

Claim 15 is rejected under 35 U.S.C. 103(a) as being unpatentable over Barefoot et al. in view of Jones (US Pat. No. 4,202,349). Barefoot et al. teaches the invention substantially as claimed, however, Barefoot et al. does not teach markings on the prosthesis. Jones teaches a stent with markings in col. 2, line 52 through col. 3, line 16 for the purpose of helping the physician to properly locate the prosthesis. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the device of Barefoot et al. by placing markings on the prosthesis in order to help the physician to properly locate the prosthesis.

Claim 16 is rejected under 35 U.S.C. 103(a) as being unpatentable over Barefoot et al. in view of Dusbabek et al. (US Pub. No. 2001/0007082). Barefoot et al. teaches the invention substantially as claimed, however, Barefoot et al. does not teach how the sheet membrane is formed. Dusbabek et al. teaches a stent where a cylinder is cut to form different structures to be used with the prosthesis in paragraphs 0074-0076 for the purpose of allowing the user to create the desired shape for the prosthesis. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the device of Barefoot et al. by using

a cut cylinder to form different structures to be used with the prosthesis in order to allow the user to create the desired shape for the prosthesis.

Claims 19-24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Barefoot et al. Barefoot et al. teaches the invention substantially as claimed except for the specific properties of size, and stiffness claimed by the Applicant. It would have been obvious to one having ordinary skill in the art at the time the invention was made to construct the prosthesis with the claimed physical characteristics, since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art.

Claims 25 and 26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Barefoot et al. in view of Silverstrini et al. (US Pat. No. 4,834,755). Barefoot et al. teaches the invention substantially as claimed, however, Barefoot et al. does not teach using elastic polyurethane in the prosthesis. Silverstrini et al. teaches a biological prosthesis using elastic polyurethane in columns 5 and 6 for the purpose of utilizing the material's biocompatibility. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the device of Barefoot et al. by using elastic polyurethane in the prosthesis in order to utilize the material's biocompatibility.

Claim 27 is rejected under 35 U.S.C. 103(a) as being unpatentable over Barefoot et al. in view of Barath (US Pub. No. 2002/0116016). Barefoot et al. teaches the invention substantially as claimed, however, Barefoot et al. does not teach inserting the device thoracoscopically. Barath teaches a vascular prosthesis that is inserted thoracoscopically in paragraphs 0027-0029 for the purpose of using the less-invasive closed-chest surgical methods. Therefore, it would

have been obvious to one of ordinary skill in the art at the time the invention was made to modify the device of Barefoot et al. by inserting the device thoracoscopically in order to use the less-invasive closed-chest surgical methods.

Response to Arguments

Applicant's arguments with respect to claims 1-29 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to ANN SCHILLINGER whose telephone number is (571)272-6652. The examiner can normally be reached on Mon. thru Fri. 9 a.m. to 4 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, David Isabella can be reached on (571) 272-4749. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/A. S./
Examiner, Art Unit 3774
/William H. Matthews/
Primary Examiner, Art Unit 3774